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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,032	10/25/2001	Marie Johannessen	5261.210-US	8734

7590 09/24/2003

Reza Green, Esq.
Novo Nordisk of North America, Inc.
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EXAMINER

SCHNIZER, HOLLY G

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N . 10/026,032	Applicant(s) JOHANNESSEN ET AL.	
	Examin r Holly Schnizer	Art Unit 1653	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondenc address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a) In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2001 .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

- 4) ☒ Claim(s) 32-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 32-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/148,440 .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10-25-01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

The Preliminary Amendment filed 10-25-01 has been entered. Claims 1-31 have been cancelled and Claims 32-41 have been added. Claims 32-41 are pending and have been considered on the merits in this Office Action.

Specification

The Specification is objected to for inconsistencies between the Drawings and the Brief Description of the Drawings. The Brief Description of the Drawings on page 5, lines 14-18 refers to minipigs Nos. a-d in lines 15 and 18. However, Figures 1 and 2 are labeled as Animal Nos. 1, 2, 3, and 4. This inconsistency may be corrected by amending the Brief Description of the Drawings to refer to Animal Nos. or Minipig Nos. 1, 2, 3, and 4 rather than a, b, c, or d. Alternatively, the drawings may be amended to be consistent with the Brief Description.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35 and 39 are indefinite because it is unclear as to whether they are properly dependent. Claims 35 and 39 depend from claims drawn to methods of treating a disease affectable by Factor VIIa or prolonging the half-life of Factor VIIa wherein the methods involve the use of modified factor VIIa. However, Claims 35 and 39 recite, "wherein the Factor VIIa is recombinant human Factor VIIa". The claims are confusing because they are unclear as to whether "the Factor VIIa" refers to the Factor VIIa that affects the disease to be treated or has a prolonged half-life, or to the modified FVIIa of the independent claims from which they depend. If "the Factor VIIa" refers to the Factor VIIa of line 1 of Claim 33, then Claim 33 is unclear as to how the method prolongs the half-life of recombinant human Factor VIIa by using a modified factor VIIa. If "the Factor VIIa" of Claims 35 and 39 are referring to the modified FVIIa, then the claims should be amended (for example, "wherein the modified FVIIa is a modified recombinant human factor VIIa". Clarification is required.

Claims 32 and 33 (and dependent Claims 34-41) are indefinite because the claims are unclear as to the metes and bounds of "substantially the same biological activity". The term "substantially" is a term of degree. Such a term of degree is allowable if the specification either defines the term or provides some standard for measuring the degree such that one of ordinary skill in the art would understand the metes and bounds of what is claimed. In the instant case, the Specification does not provide any such definition or standard for determining what activities are considered "substantially the same". Moreover, factor VIIa activities vary from assay to assay, from different purifications, or from different treatments. For example, the present

specification shows that the biological activity of the same factor VIIa is different when measuring after subcutaneous injection versus intravenous administration (see Table 3). Claims 34-41 are indefinite because they depend from Claims 32 and 33 yet do not correct the ambiguities therein.

Claims 32 and 33 (and dependent Claims 34-41) are indefinite as what is considered "authentic". "Authentic" means real or genuine. Therefore, does "authentic" refer to all factor VIIa proteins isolated from nature regardless of their sequences? Or, does "authentic" include recombinant factor VIIa sequences and if so, which sequences are considered "authentic"? In the present claims, the "authentic" factor VIIa is used as a standard to measure activity levels. However, in order to determine when a particular modified factor VIIa has substantially the same activity for blood coagulation as "authentic" factor VIIa, knowledge of the activity of the "authentic" factor VIIa or knowledge of its sequence is required. Therefore, in this regard, the claims are unclear because the identity of "authentic" factor VIIa is unclear. Clarification is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 1653

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 32-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,310,183 in view of Nicolaisen et al. (U.S. Patent No. 5,580,560). Although the conflicting claims are not identical, they are not patentably distinct from each other.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claim. See, e.g. *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

In the present case, the claims of U.S. Patent No. 6,310,183 (the '183 patent) and the instant application are all drawn to methods for treatment by subcutaneously administering an effective amount of factor VIIa or methods for prolonging the biological half-life of factor VIIa being administered by administering a composition comprising factor VIIa by subcutaneous injection. The claims of the '183 patent and the instant application differ in that the methods of the '183 patent claims are open to using any factor VIIa whereas the methods of the instant application claims are limited to using modified factor VIIa. However, the '183 patent defines factor VIIa as including authentic factor VIIa or modified factor VIIa provided that such factor VIIa has substantially the same biological activity for blood coagulation as authentic factor VIIa (see Col. 5, lines 11-15). Therefore, the claims of the '183 patent encompass using modified factor VIIa.

The benefits of using a modified factor VIIa in the method taught in the '183 patent would have been obvious to one of ordinary skill since modified factor VIIa molecules were available that had increased half, as evidenced by Nicolaisen et al. Therefore, it would have been obvious to one of ordinary skill in the art to use a modified factor VIIa, such as that disclosed in Nicolaisen et al., in the methods of treatment and prolonging the biological half life of factor VIIa taught in the '183 patent. One would have been motivated to use the modified factor VIIa of Nicolaisen et al. in the methods of the '183 patent to optimize the bioavailability of factor VIIa after administration into a patient; a common goal of both Nicolaisen et al. and the '183 patent.

Conclusions

No claims are allowable for the reasons described above.

A thorough search of the art did not reveal any teaching or suggestion that the subcutaneous administration of FVIIa, specifically, would result in prolonged half-life of the FVIIa as compared to the half-life of factor VIIa administered by other methods. Therefore, for this reason and for the reasons described in parent Application No. 09/148,440, it appears that the claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-


Application/Control Number: 10/026,032
Art Unit: 1653

Page 7

3722. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Holly Schnizer
September 16, 2003


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800

Notice of References Cited	Application/Control No. 10/026,032	Applicant(s)/Patent Under Reexamination JOHANNESSEN ET AL.	
	Examiner Holly Schnizer	Art Unit 1653	Page 1 of 1

U.S. PATENT DOCUMENTS

★		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-,580,560	12-1996	Nicolaisen et al.	424/94.64
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

★		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

★		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a))
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

(No Model.)

I. SCOVILLE.
FRUIT SLICING MACHINE.

No. 580,560.

Patented Apr. 13, 1897.

Fig. 1.

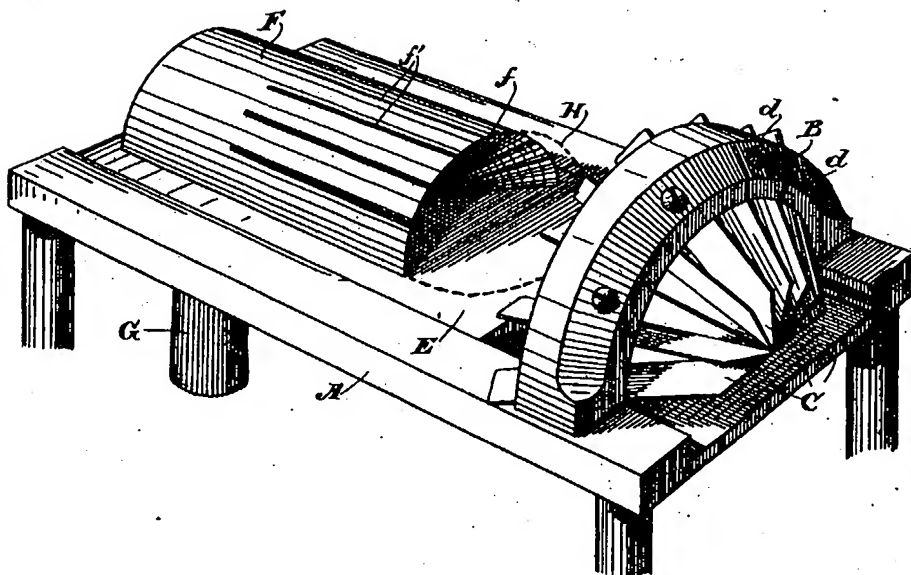
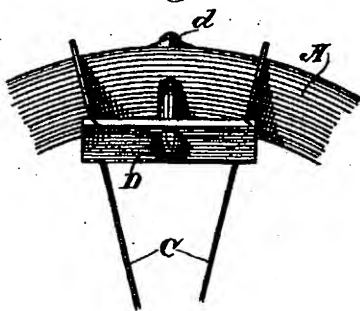


Fig. 2.



Witnesses,
J. H. Amee
J. F. Ascheck

Inventor,
Ives Scoville
By Deway & Co. attys

UNITED STATES PATENT OFFICE.

IVES SCOVILLE, OF OAKLAND, CALIFORNIA.

FRUIT-SLICING MACHINE.

SPECIFICATION forming part of Letters Patent No. 580,560, dated April 13, 1897.

Application filed August 31, 1896. Serial No. 604,456. (No model.)

To all whom it may concern:

Be it known that I, IVES SCOVILLE, a citizen of the United States, residing at Oakland, county of Alameda, State of California, have invented an Improvement in Fruit-Slicing Machines; and I hereby declare the following to be a full, clear, and exact description of the same.

My invention relates to the class of slicing-machines, and particularly to machines for slicing fruit, especially peaches after they have been peeled and the stones or pits removed.

It consists of the parts and the constructions and combinations of parts hereinafter described and claimed.

Figure 1 is a perspective of my machine. Fig. 2 is a detail showing the means for fastening the knives.

A is a suitable stand or frame. Upon this is fixed a knife-support in the form of an arch B, and to this are secured in a suitable manner the knives C. These are arranged or disposed in radial planes, and in the best form of the machine they are also set at an acute angle to the plane of the bed or frame, which said plane is that in which the movement of the fruit to the knives takes place. The knives may be secured to the arch, as I have stated, in any suitable manner, and for this purpose I have here shown them as being attached by means of yokes D and bolts d.

In the frame or stand A is fitted and adapted to slide a plate E, upon which is secured the fruit-holder F. This may be of any suitable material, preferably of metal. It is semicircular in cross-section, and its front end is recessed out to form a socket f, approximately a quarter of a sphere, and from this recess the carrier is slitted or slotted backwardly, as shown at f', said slots being separated by the width of the intercutting spaces, whereby the carrier may pass through between the knives. A reciprocating motion is imparted to this fruit-holder by any suitable means. In practice and for large machines there would be a power mechanism of some kind or a foot or treadle device or a hand-crank; but for the sake of illustration merely I have here shown a handle G, by which the reciprocation may be effected.

The operation of the machine is as follows:

In the preparation of peaches for slicing it is usual to peel them and remove their pits or stones. These operations leave the fruit in halves. One of these halves, such as is represented by H, is laid flat down upon the sliding plate E, so that its circumference fits within the recess of the holder F. Said holder is now moved toward the knives and the fruit is carried through between them and is thereby cut into radial slices. All these slices will be of the same size and appearance and all may be used, thus avoiding waste, and at the same time providing an attractive-looking product.

Although I have herein described the fruit as being carried to the knives, it is obvious that a reverse movement may be provided for by having the fruit stationary and the knives carried to the fruit without departing from the spirit of my invention. It will also be noted that in this operation, by reason of the knives being set at an acute angle to the plane or path of movement of the fruit, the cutting action will be more in the nature of a draw cut in that it does not take place all at once, but is gradual in its effect.

Having thus described my invention, what I claim as new, and desire to secure by Letters Patent, is—

1. In a fruit-slicer, the combination, with means for slicing the fruit, of a fruit-holder having a recessed end to form a segmental socket to receive the end of the fruit, and having a horizontal forwardly-projecting support upon which the fruit rests while being advanced to the slicing devices.

2. In a fruit-slicer, the combination, with means for slicing the fruit, of a horizontally-slidable fruit-holder having a segmental socket in one end into which the end of the fruit is placed, and having an underlying support or bottom, movable with it and upon which the severed side of the fruit rests during the slicing operation, said holder being slitted or slotted from the recessed end backwardly to permit the fruit to pass the slicing devices.

3. In a fruit-slicer, the combination, of a series of radially-disposed knives and a slidable horizontal support or plate, for the fruit, provided with a holder made semicircular in cross-section and having its front end re-

cessed to form a socket which approximates a segment and into which the fruit is received, said holder being slitted or slotted from its socket end backwardly.

5 4. In a machine for slicing fruit, the combination, of a frame or stand, an arched knife-support secured thereto, a series of radially-disposed knives in said support, yokes and bolts for securing the knives to the arch and
10 a horizontal slide in the frame, upon which the fruit is supported, having a slitted or slotted holder with a socket end to receive the fruit and hold it while it is being carried to and operated upon by the knives.

15 5. In a machine for slicing fruit, the combination, of a series of fixed radially-disposed knives and a horizontally-slidable support for halved fruit, comprising a holder of arched form having its forward end slitted or slotted
20 and provided with a curved recess to receive one end of the fruit to be sliced.

6. In a machine for slicing fruit, the combination of fixed knives or cutters, a horizontally-slidable plate upon which the flat side
25 of a severed or divided fruit is placed and an arched, longitudinally-slitted holder on said plate back of its front edge, having its front

end provided with a curved recess to receive the circumference of the fruit.

7. In a fruit-slicing machine, the combination of a series of radially-disposed knives and a horizontally-slidable fruit-holder, consisting of a slotted block adapted to receive the knives whereby the fruit is cut into radial slices, said block having a recessed front to
30 receive the fruit and a floor extension on which the fruit is supported.

8. A fruit-slicing machine comprising a suitable frame or stand, an arch carried thereby, a series of radially-disposed inclined
40 knives carried by the arch, a plate mounted and adapted to slide in said frame or stand and form a support for the severed side of the fruit prior to and during the slicing operation, and a fruit-holder carried by said plate
45 back of its front edge, and having a recessed front for the end of the fruit, with backwardly-extending slots to receive the knives.

In witness whereof I have hereunto set my hand.

IVES SCOVILLE.

Witnesses:

S. H. NOURSE,

WM. F. BOOTH.

14 6500 Bldg./Room LHM

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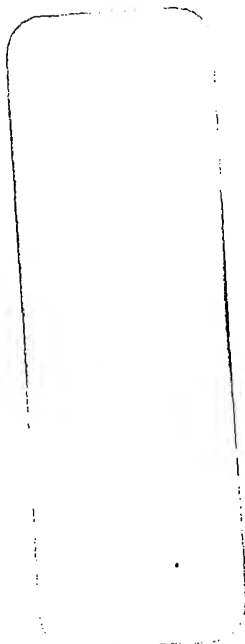
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